

105 CMR 721.000: STANDARDS FOR PRESCRIPTION FORMAT AND SECURITY IN MASSACHUSETTS

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721.001: Purpose

The purpose of 105 CMR 721.000 is to specify the requirements for prescription format and security in Massachusetts.

721.002: Citation

105 CMR 721.000 shall be known as 105 CMR 721.000: *Standards for Prescription Format and Security in Massachusetts*.

721.003: Scope and Application

105 CMR 721.000 establishes the standards for format and security in the Commonwealth that all prescriptions issued by practitioners or reduced to writing by pharmacists must meet in order to comply with M.G.L. c. 112, § 12D and M.G.L. c. 94C.

721.010: Definitions

The terms used herein shall have the meanings set forth in 105 CMR 721.010. Terms defined in M.G.L. c. 112, § 12D and c. 94C, § 1 and not defined herein shall have the meanings set forth therein when used in 105 CMR 721.000, unless the context clearly requires a different interpretation.

Authentication means that the identities of the parties sending and receiving electronic prescription data are duly verified.

Confidentiality means that only authorized persons have access to prescription data.

Content Integrity means that the electronic prescription data have not been altered or compromised in transmission.

Drug Product means the final dosage form of a drug that is marketed under a brand or generic name.

Electronic Signature means an electronic sound, symbol or process attached to or logically associated with a prescription record and executed or adopted by a practitioner with the intent to sign said prescription record.

Technical Non-repudiation means that parties to the generation, transmission, receipt or storage of an electronic prescription cannot reasonably deny having participated in said activities.

721.020: Prescription Formats

(A) Every prescription written in the Commonwealth must be in a prescription format that conforms to the following requirements:

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- (1) a prescription must permit the practitioner to instruct the pharmacist to dispense a brand name drug product by indicating “no substitution”, provided that:
 - (a) the indication of “no substitution” is not the default indication;
 - (b) the prescription indicates that “Interchange is mandated unless the practitioner indicates ‘no substitution’ in accordance with the law”; and
 - (c) the indication of “no substitution” is a unique element in the prescription and shall not be satisfied by use of any other element, including the signature;
- (2) if the prescription is paper-based, including but not limited to a prescription that is transmitted via facsimile or similar technology, or reduced to writing by a pharmacist, the prescription must be on a form that contains a signature line for the practitioner's signature on the lower portion of the form. Hospital and clinic prescription forms shall contain a line directly below the signature line for the practitioner to print or type his/her name. Below the signature line, or in the case of hospital and clinic prescription forms, below the line provided for the practitioner to print or type his/her name, there shall be a space in which the practitioner may indicate "no substitution". Below this space shall be printed the words "Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law”;
- (3) if the prescription is transmitted electronically, the practitioner shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form;
- (4) the name and address of the practitioner shall be clearly indicated on the prescription. A hospital or clinic prescription shall have the name and address of the hospital or clinic clearly indicated on the prescription;
- (5) the prescription shall contain the following information:
 - (a) the registration number of the practitioner;
 - (b) date of issuance of the prescription;
 - (c) name, dosage, and strength per dosage unit of the controlled substance prescribed, and the quantity of dosage units;
 - (d) name and address of the patient, except in a veterinary prescription;
 - (e) directions for use, including any cautionary statements required; and
 - (f) a statement indicating the number of times to be refilled.

(B) Prescriptions for certified nurse midwives, nurse practitioners, psychiatric nurses and physician assistants shall also contain the name of the supervising physician.

721.030: Security Standards for Prescriptions

- (A) A prescription may be transmitted electronically provided that:
 - (1) if said prescription is for a controlled substance in Schedules II through V, it is validated and authenticated in accordance with M.G.L. c. 94C and applicable Department regulations, if any, and 21 CFR 1306 and other applicable federal regulations;
 - (2) if said prescription is for a controlled substance in Schedule VI it is validated and authenticated in accordance with requirements in M.G.L. c. 94C and applicable Department regulations for oral prescriptions or by utilizing a system that includes:
 - (a) a combination of technical security measures, such as, but not necessarily limited to, those listed in Security Standards for the Protection of Electronic Protected Health Information (HIPAA), 45 CFR Part 164, Subpart C, § 164.312, to ensure a reasonable and appropriate level of:
 1. practitioner and dispenser authentication;
 2. technical non-repudiation;
 3. content integrity; and
 4. confidentiality.
 - (b) an electronic signature that is:
 1. unique to an identified practitioner;
 2. originated solely by and under the ultimate control of the practitioner; and
 3. capable of verification.
 - (c) reasonable and appropriate security measures to invalidate a prescription if either the electronic signature or the prescription record to which it is attached or logically associated is altered or compromised; and

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(3) said prescription meets any other generally applicable requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) and related regulations.

(B) An electronic signature that meets the requirements of 105 CMR 721.031 shall have the full force and effect of a handwritten signature on a paper-based written prescription.

(C) A paper-based written prescription must be written and signed by the practitioner in accordance with M.G.L. c. 94C, § 23 and 105 CMR 721.000.

721.040: Invalid Prescriptions

(A) A prescription in a format that does not conform to 105 CMR 721.000 is invalid and shall not be filled.

(B) A prescription that does not meet the security requirements of 105 CMR 721.000 is invalid and shall not be filled.

721.050: Prescribing More Than One Drug Product

Practitioners who wish to prescribe more than one drug product, with the same or different dispensing instructions, shall place each prescription on a separate prescription form or record. More than one drug product may be prescribed in the hospital setting on a single form or record provided, however, that the prescription provides clear directions for use and interchange of each drug product.

REGULATORY AUTHORITY

105 CMR 721.000: M.G.L. c. 30A, § 2; c. 94C, § 6; c. 111, § 3; and c. 112, § 12D.

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